Office Action Summary	Application No. 08/475,822	Applicant(s) Alizon et al.
	Examiner Railey	Group Art Unit 1805

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *11-18* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *11-18* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) *07/158,652*.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1805.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-22 of copending application Serial No. 08/202,239. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to the identical nucleic acid sequences to be used as probes in the diagnostic hybridization methods of the instant application. It appears that application Serial Nos. 08/202,236 and 08/177,920 (the parent application of the instant application 08/475,822) were filed by applicant as divisional applications from the parent application Serial No. 07/158,652. There is no

evidence that the PTO has set forth a restriction requirement between the nucleic acids of application Serial No. 08/202,239 and the methods of use of those nucleic acids as probes in the parent application Serial No. 08/177,920.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to teach adequately how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Applicant discloses the complete nucleic acid sequence of the genome of LAV, now known as a specific isolate of HIV-1. The sequence is translated into each of three potential reading frames in order to locate all significant open reading frames and assign gene locations. Applicant's claims are drawn to *in vitro* diagnostic methods for detecting the presence or absence of nucleic acid of HIV-1 in a biological sample by using specific cloned nucleic acids as probes. These probes may also be labeled with any of several types of labels. Kits comprising this cloned nucleic acid to be used in the *in vitro* diagnostic assay are also claimed. The nucleic

acids used as probes in the diagnostic assays are ORF-Q, ORF-R, ORF-1, ORF-2, ORF-3, ORF-4 and ORF-5. Applicant's preliminary amendment, paper No. 6, filed 6 January 1994, at page 40 cites the specification at pages 12, line 34 through page 13, line 5; and page 14, lines 17-32 for support for the claims. However, the specification as filed does not teach how to use the invention for the claimed diagnostic methods which include these nucleic acids as a probe. It is not demonstrated that the nucleic acids hybridize specifically with HIV-1 to detect the presence or absence of this virus in a biological sample. No specific conditions or methods are given which would allow discrimination between HIV-1 and other retroviruses, such as HTLV-I, HTLV-II or HIV-2 when using the claimed probe. How specific is each claimed probe for any given variant of HIV-1; will it detect strains other than LAV? How are these various "biological samples" to be prepared for the hybridizations such that HIV-1 is detected specifically, reproducibly and accurately? Also, the composition of the kits to effect such specific diagnostic assays is not described. What are the "reagents" to be used and what comprises the "biological reference sample" to enable the skilled artisan to use such a kit?

Applicant was provided with a reference by Hahn et al. [Nature **312**:166-169 (1984)] which demonstrates that at the time of the filing of the instant application, it was known that cross-hybridization indeed does occur between the sequences of HIV and members of the HTLV family; even at stringent conditions. See Figure 4. Given the lack of teaching in the specification of specific hybridization using applicant's probes and the evidence of Hahn et al.

showing cross-hybridization to members of the HTLV family, the specification as filed does not provide an enabling disclosure for using such probes in hybridization assays to detect HIV-1 specifically.

Claims 11-18 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Art Unit 1805 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for Art Unit 1805 is (703) 308-0294.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. F. Railey, whose telephone number is (703) 308-0281. The examiner can normally be reached on Monday-Thursday, and alternate Fridays, from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mindy Fleisher, can be reached at (703) 308-0407. The fax phone number for Art Unit 1805 is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Johnny F. Railey II, Ph.D.
June 20, 1996

MINDY FLEISHER
SUPERVISORY PATENT EXAMINER
GROUP 1800